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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,008	11/25/2003	Fu-Pao Tsao	CL/V-32800A	6999

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EXAMINER

OGDEN JR, NECHOLUS

ART UNIT	PAPER NUMBER
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1751

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/722,008

Applicant(s)

TSAO ET AL.

Examiner

Necholus Ogden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. Claims 1, 3-10, 12-14, 16-19, 21 and 23 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schwind et al (2002/0155961).

Schwind et al disclose a lens care product comprising 5-20 g/l of dexpanthenol; 10 to 30 g/l of D-sorbitol; 0 to 5 g/l of sodium chloride or potassium chloride; 0.0005 to 0.05 g/l of PHMB; 0.1 to 2 g/l of EDTA; disodium phosphate buffers; water; a surface active substance; viscosifier; a pH value of 6 to 8 (see 0030-0032) and 0.072 g/l of disodium hydrogen phosphate (0039). Schwind et al further teach that the tonicity is measured in the range of 200 to 450 milliosmol (col. 1, 0007).

As this reference teaches all of the instantly required it is considered anticipatory.

Alternatively, Schwind et al is silent with respect to reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5. However, it would have been obvious to the skilled artisan in the contact lens disinfecting art to expect the compositions of Schwind et al to encompass the *C. albicans* in the requisite log reduction and time of contact because Schwind et al teaches all of the claimed components for the purpose of disinfecting and absent a showing to the contrary one of ordinary skill would expect similar contact lens cleaning and disinfecting characteristics.

2. Claims 1, 3-8, 12, 14-15, 17-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Groemminger et al (6,872,695).

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Groemminger et al disclose a method of cleansing contact lens comprising a thickening agent such as PVP (col. 4, line 42); surfactants such as polyaxamine and tyloxapol (col. 4, line 66 and col. 5, line 35); an antimicrobial such as PMHB in an amount from 0.00001 to 5%; osmolality-adjusting agent such as glycerol to provide osmolality of 270 mOsm/kg and a pH of 5-6 (col. 6, lines 26-59); a sequestering or chelating agent such as EDTA (col. 6, lines 60-62) and tonicity agents such as sodium chloride in amount from 0.01 to 2.5% (col. 7, lines 1-11).

As this reference teaches all of the required, it is considered anticipatory.

Alternatively, Groemminger et al is silent with respect to reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5. However, it would have been obvious to the skilled artisan in the contact lens disinfecting art to expect the compositions of Groemminger et al to encompass the *C. albicans* in the requisite log reduction and time of contact because Groemminger et al teaches all of the claimed components for the purpose of disinfecting and absent a showing to the contrary one of ordinary skill would expect similar contact lens cleaning and disinfecting characteristics.

Claim Rejections - 35 USC § 103

3. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwind et al (2002/0155961) in view of Hu et al (6,037,328).

4. Schwind et al is relied upon as set forth above. Specifically, Schwind et al do not teach the inclusion of tyloxapol as an additional surfactant.

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5. Hu et al disclose a method and composition for treating contact lens.

Specifically, Hu et al disclose the use of an effective amount of a poloxamer and a tyloxapol (col. 2, lines 55-61).

It would have been obvious to one of ordinary skill in the art to include an additional surfactant such as tyloxapol because Hu et al teach that the combination of surfactants has been found to be not only effective in preventing the deposition of lipids, but is comfortable for use in the eye (col. 3, lines 60-65). Therefore, one of ordinary skill would have motivated to include the additional surfactant, tyloxapol in view of the teachings disclosed in Hu et al.

6. Claims 20, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwind et al in view of Groemminger et al (6,872,695).

Schwind et al is relied upon as set forth above. Specifically, Schwind et al do not teach the inclusion of polyvinyl pyrrolidone.

Groemminger et al is relied upon as set forth above. Specifically, Groemminger et al teach the use of polyvinyl pyrrolidone as a thickening agent or pseudoplastic (viscosity affecting) (col. 4, line 28-42) and Schwind et al require the use of substances that affect the viscosity (0032). Therefore, one of ordinary skill in the contact lens art would have include PVP to the compositions of Schwind et al to affect the viscosity of the contact lens composition as suggested by Groemminger et al for the purpose of affecting the shear liquification of gel upon blinking (col. 4, lines 27-29).

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7. Claims 1-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of 6261546; 1-15 of 5858996; 1-12 of 5846919; 1-5 of 5807585; 1-5 of 5683993; 1-11 of 5576276 and claim 1 of 5298182.

8. Claims 1, 3-10, 13-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/963,972; 11/078,209; 11/212,957 and 11/212,959.

Response to Arguments

9. Applicant's arguments filed 7-10-2006 have been fully considered but they are not persuasive.

Applicant argues that Schwind et al do not teach or suggest the lens care composition of the claimed invention. Specifically one that includes less than 0.1% phosphate buffer, less than 1 ppm of a polymeric antimicrobial; and a total concentration of chloride ions and phosphate ions below 1500 ppm.

The examiner contends and respectfully disagrees and directs applicants attention to Schwind et al where said reference does not require a phosphate buffer but includes said buffer with a plethora of other ingredients such as tris (hydroxymethyl) aminomethane (TRIS). With respect to the polymeric agent being less than 1 ppm Schwind et al teach that said agent is present in an amount from 0.1 ppm (0012). With further respect to the total concentration of chloride ions and phosphate ions being below 1500 ppm. The examiner directs applicant's attention to (0030) that specifically teaches 0 g/l of sodium chloride or potassium chloride and, as stated above, phosphate

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is not a required component but one of many that may be included as a buffer material. Note, see examples 4, 5 and 8 that do not include phosphate ions or chloride ions in said lens compositions. Note, the less than 1500 ppm reads on optional or zero and Schwind et al specifically teach several preferred embodiments that do not comprise chloride and phosphate ions. Therefore the rejection is maintained.

Applicant argues that Groemminger et al do teach or suggest the lens core composition because Groemminger et al do not teach phosphate buffer at any level. Applicant further argues that Groemminger et al make no mention or teachings or suggestion of the total concentration of chloride ions and phosphate ions and therefore cannot anticipate or render obvious.

The examiner contends and agrees that Groemminger et al makes no mention of phosphate ions and/or chloride ions as suggested by applicant, which encompasses the claimed invention that is substantially free of phosphate and chloride ions and/or less than 0.1% of a phosphate buffer. Accordingly, Groemminger et al is silent with respect to phosphate buffers but does include buffers in an amount from 0.00001 to 0.5% by weight (col. 4, lines 24-43).

The obviousness-type double patenting rejections are maintained because the chloride ions and phosphate ions are optional ingredient and therefore their remains an overlap of subject matter.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Necholus Ogden whose telephone number is 571-272-1322. The examiner can normally be reached on M-T, Th-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas McGinty can be reached on 571-272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Nicholas Ogden
Primary Examiner
Art Unit 1751

No
10-28-2006